

Food and Drug Administration, HHS

§ 520.45a

- 520.2520f Trichlorofon granules.
520.2520g Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.
520.2582 Triflupromazine hydrochloride tablets.
520.2598 Trilostane.
520.2604 Trimeprazine tartrate and prednisolone tablets.
520.2605 Trimeprazine tartrate and prednisolone capsules.
520.2610 Trimethoprim and sulfadiazine tablets.
520.2611 Trimethoprim and sulfadiazine paste.
520.2612 Trimethoprim and sulfadiazine oral suspension.
520.2613 Trimethoprim and sulfadiazine powder.
520.2640 Tylosin.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine.

(a) *Specifications.* Each tablet contains 5, 10, or 25 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.25 to 1.0 mg per pound (lb) body weight orally.

(ii) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight orally.

(ii) *Indications for use.* As a tranquilizer.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10165, Mar. 5, 2010]

§ 520.44 Acetazolamide sodium soluble powder.

(a) *Specifications.* The drug is in a powder form containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an aid in the treatment of mild

congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered orally at a dosage level of 5 to 15 milligrams per pound of body weight daily.¹

(3) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 45.5 milligrams (mg) (4.55 percent) or 113.6 mg (11.36 percent) albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Cattle.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/pound (lb) body weight (10 mg/kilogram (kg)) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni* and *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriiformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.45b

(iii) *Limitations.* Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls.

(2) *Sheep.* Administer 4.45 or 11.36 percent suspension:

(i) *Amount.* 3.4 mg/lb body weight (7.5 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica* and *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams.

(3) *Goats.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/lb body weight (10 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For the treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats.

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to does during the first 30 days of pregnancy or for 30 days after removal of bucks.

[73 FR 11027, Feb. 29, 2008]

§ 520.45b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

21 CFR Ch. I (4–1–11 Edition)

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest.

(a) *Specifications.* Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.36 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use.* For suppression of estrus in mares.